1.0 INTRODUCTION

1.1 Background

The Federal Water Pollution Control Act, commonly known as the Clean Water Act (CWA), was enacted in 1972 with the objective of "*restoring the chemical, physical, and biological integrity of the Nation's waters*." Several goals and policies were established in the Act, including the following:

- Eliminating the discharge of pollutants into navigable waters by 1985;
- Wherever attainable, achieving an interim goal of water quality that provides for the protection and propagation of fish, shellfish, and wildlife, and provides for recreation in and on the water by November 1, 1983; and
- Prohibiting the discharge of toxic pollutants in toxic amounts.

In the 28 years since the CWA was enacted, the U.S. Environmental Protection Agency (EPA) and States authorized to administer EPA's National Pollutant Discharge Elimination System (NPDES) permitting program have made significant progress toward achieving these goals. NPDES is designed to control toxic discharges, implement a water quality standards program, and restore waters to "fishable and swimmable" conditions. A point source that discharges pollutants to waters of the United States must do so under the terms and conditions of an NPDES permit. In setting these terms and conditions, EPA and the States have integrated their control of toxic pollutants through combined use of three approaches [*Technical Support Document for Water Quality-based Toxics Control* (USEPA 1991a, referred to as the TSD)]:

- Chemical-specific controls,
- Whole effluent toxicity (WET) controls, and
- Biological criteria/bioassessments and bioassays.

The WET approach to protection of water quality is the primary subject of this document.

In 1989, EPA defined whole effluent toxicity as "*the aggregate toxic effect of an effluent measured directly by an aquatic toxicity test*" [54 Federal Register (FR) 23868 at 23895, June 2, 1989]. Aquatic toxicity tests are laboratory experiments that measure the biological effect (e.g., growth, survival, and reproduction) of effluents or receiving waters on aquatic organisms. In aquatic toxicity tests, groups of organisms of a particular species are held in test chambers and exposed to different concentrations of an aqueous test sample, for example, a reference toxicant, an effluent, or a receiving water. Observations are made at predetermined exposure periods. At the end of the test, the responses of test organisms are used to estimate the effects of the toxicant or effluent.

In the early 1980s, EPA published methods (USEPA 1985, 1988, 1989) for estimating the short-term acute and chronic toxicity of effluents and receiving waters to freshwater and marine organisms. WET data gathered in the 1980s indicated that approximately 40 percent of NPDES facilities nationwide discharged an effluent with sufficient toxicity to cause water quality problems. Further reductions in the toxicity of wastewater discharges were necessary to achieve compliance with narrative water quality standards expressed as "no toxics in toxic amounts." In response to these findings, EPA implemented a policy to reduce or eliminate toxic discharges. The *Policy for the Development of Water Quality-based Permit Limitations for Toxic Pollutants* (49 FR 9016, March 9, 1984) introduced EPA's integrated toxics control program. To support this policy, EPA developed the TSD (USEPA 1991a). The TSD provides guidance to

regulators in implementing WET testing requirements in NPDES permits. In 1989, EPA promulgated regulations specifying procedures for determining when water quality-based effluent limitations are required in NPDES permits [40 CFR, 122.44(d)]. On October 26, 1995, EPA promulgated WET test methods (USEPA 1993, 1994a, and 1994b) and added them to the list of EPA methods approved under Section 304(h) of the CWA (40 CFR, 136) for use in the NPDES program. Although the rulemaking was challenged in court, that challenge has been stayed pending completion of a settlement agreement. The rulemaking remains in force and effect unless and until EPA takes further action.

1.2 Effect of This Guidance

This document attempts to clarify several issues regarding WET variability and reaffirms EPA's earlier guidance and recommendations published in the TSD (USEPA 1991a). This document is intended to provide NPDES regulatory authorities and all stakeholders, including permittees, with guidance and recommendations on how to understand and account for measurement variability in WET testing. The document's recommendations and conclusions are detailed in Section 7. Appendix C provides sample NPDES permit language reflecting these recommendations.

The most significant recommendation is to use and report the values for the percent minimum significant difference (PMSD) with all WET data results. The minimum significant difference (MSD) is the smallest difference that can be distinguished between the response of control organisms and the response of test organisms at each concentration of the WET test dilution series. The MSD provides an indication of the within-test variability and test method sensitivity. Using this information, the regulatory authority and permittees can better evaluate WET test results.

This document also recommends the following:

- Continue to use the EPA TSD statistical approach for NPDES permit limit development (no test method variability adjustments are needed);
- Collect and evaluate a sufficient number of representative effluent samples;
- Verify effluent toxicity data carefully along with reference toxicant data;
- Maintain good communication between the regulatory authority and permittee throughout all phases of the permitting process;
- Implement the PMSD to evaluate both WET and reference toxicant data to minimize within-test method variability and increase test sensitivity;
- Maintain laboratory checks with good laboratory certification programs to encourage experienced laboratories and skilled analysts for the toxicity testing program for individual WET laboratory performance.

1.3 Three Goals of This Document

EPA prepared this document to achieve the following three goals:

1. Quantify the variability of promulgated test methods and report a coefficient of variation (CV) as a measure of test method variability (see Chapter 3 and Appendix A).

2. Evaluate the statistical methods described in the *Technical Support Document for Water Quality-Based Toxics Control* (TSD) for determining the need for and deriving WET permit conditions (see Chapter 6 and Appendix G).

3. Suggest guidance for regulatory authorities on approaches to address and minimize test method variability (Chapter 6). In addition, the document is intended to provide guidance to regulatory authorities, permittees, and testing laboratories on conducting the biological and statistical methods and evaluating test effect concentrations (Chapter 5).

This document does not address effluent variability. It does, however, discuss how handling effluent samples can affect tests. Chapter 2 provides definitions of terms used and discusses the ways in which variability can be quantified. Chapter 3 describes the variability of the effect concentration estimates (EC25, LC50, and NOEC) and the variability of endpoint measurements (survival, growth, and reproduction). Chapter 4 discusses WET variability in the context of chemical-specific method variability. Chapter 5 provides guidance to permittees, testing laboratories, and regulatory authorities to minimize test method variability. Chapter 6 provides guidance to regulatory authorities on how to determine reasonable potential (RP) and derive permit limits or monitoring triggers and evaluate self-monitoring data. Chapter 7 presents EPA's principal conclusions. Chapter 8 is a bibliography containing a list of documents cited herein and additional reading material.

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